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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,393	12/21/2001	Stephen Quirk	11301-1170 (44039-250928)	1033
22827	7590	09/01/2006	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/026,393	<b>Applicant(s)</b> QUIRK ET AL.	
	<b>Examiner</b> Sheridan L. Swope	<b>Art Unit</b> 1656	

**-The MAILING DATE of this communication appears on the cover sheet with the correspondence address -**

THE REPLY FILED 11 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 82-96.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☒ Other: PTO-892.

Applicants response of August 11, 2006 is acknowledged; no claims have been cancelled, amended, or added. Claims 82-96 are pending.

In response to the rejection of Claim 90 under 35 USC 112, first paragraph, for lack of enablement and insufficient written description, Applicants argue that Figures 1C, 3, and 4 as well as the specification at pages 7 and 10-11 teach identifying two or more metalloproteinases using the same signal element. It is acknowledged that the specification (page 10, para 2) teaches that a protease can be detected by exposing a sample to "a signal element" and at least one target antibody. Said paragraph also states that such a method can be used to simultaneously detect more than one enzyme. However, all of Figures 1C, 3, and 4, and pages 7 and 10-11 of the specification teach the use of a capture antibody to separate and localize each target protease into a reactions site, wherein the captured proteases are visualized using a second protease-specific antibody labeled with a signal element. Claim 90 fails to recite steps using a protease-specific capture antibody to separate and localize each target protease into a reactions site. The specification fails to teach, without using a protease-specific capture antibody to separate and localize each target protease into reactions sites, how to detect any specific protease in a mixed sample using target antibodies all labeled with the same signal element. For these reasons and those presented in the prior actions, rejection of Claim 90 under 35 USC 112, first paragraph, for lack of enablement and insufficient written description, is maintained.

In response to the rejection of Claims 82-96 under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Sodek, 1992, Applicants make the following arguments.

- (A) None of the listed references teach or suggest simultaneously detecting a plurality of metalloproteinases.
- (B) Sorsa et al provide no incentive for detection of multiple MMPs in a sample.
- (C) Rowe et al do not describe a method for detecting a plurality of proteins or enzymes in a mixed sample.
- (D) Sodek et al do not describe a method for detecting a plurality of metalloproteinases in a mixed sample.
- (E) No proper incentive exists to combine the references as suggested because the prior art teaches a high level of unpredictability.

These arguments are not found to be persuasive for the following reasons.


(A) Reply: Because the instant rejection is under 35 USC 103(a), not 102, none of the listed references is required to teach or suggest simultaneously detecting a plurality of metalloproteinases.

(B) Reply: As stated in the prior action, it is Sodek et al, not Sorsa et al, that provide motivation to detect multiple MMPs in a sample.

(C) Reply: Rowe et al describe a method for detecting a plurality of analytes in a mixture, wherein the analytes are a bacteria, a virus, and a protein. It is acknowledged that the bacteria and virus are not proteins. However, the skilled artisan would know that, more likely than not, the capture antibodies used by Rowe et al were directed to protein components on the surface of the bacteria and virus. Therefore, the method of Rowe et al detects a plurality of proteins in a mixture (Fig 4).

(D) Reply: See (A).

(E) Reply: The reasons for motivation to combine, based on the desire to determine the presence of metalloproteinases in periodontal samples, as taught by Sodek et al, are described in the prior action. The Examiner cannot address Applicants' assertion that the art teaches a high level of unpredictability because (i) Applicants do not state what aspect of the invention is unpredictable and (ii) do not provide art in support of said unpredictability, so that said art can be evaluated by the Examiner. However, in light of the teachings of Rowe et al, methods for detecting a plurality of analytes in a mixed sample were known in the art. Also, see Silzel et al, 1998, Pritchard et al, 1995, and Rowe et al, 1999b, all of which are cited in Rowe et al, 1999 (pg 3846, para 1) as disclosing array sensors for detecting multiple proteins in a mixture.

  
SHERIDAN SWOPE, PH.D.  
PRIMARY EXAMINER